

Serial No. 10/806,795

Dkt.: P-9006.04

Filing Date: March 23, 2004

Title: HEMOSTATIC SYSTEM AND COMPONENTS FOR EXTRACORPOREAL CIRCUIT

### Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks presented herein, is respectfully requested.

Claims 1-2, 7, 11-12, 17 and 20 are amended, claims 3-6 and 13-16 are canceled, and claims 21-30 are newly added. As a result, claims 1-2, 7-12 and 17-30 are the pending claims.

New claims 21-30 and the amendments to claims 1-2, 7, 11-12, 17 and 20 are fully supported by the specification.

The specification is amended to provide priority data and to correct a typographical error.

No new matter has been added by way of these amendments.

### The 35 U.S.C. § 102(b) Rejection

The Examiner rejected claims 1-5, 10-14 and 20 under 35 U.S.C. § 102(b) as being anticipated by Arp (U.S. Patent No. 4,401,431). The cancellation of claims 3-5 and 13-14 renders this rejection moot as to claims 3-5 and 13-14. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

The standard for anticipation is one of strict identity, and to anticipate a claim for a patent a single prior art source must contain all its elements. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 USPQ2d 90 (Fed. Cir. 1986); In re Dillon, 16 USPQ2d 1987 (Fed. Cir. 1990).

Furthermore, there must be no difference between the claimed invention and the disclosure, as viewed by a person of ordinary skill in the art. Scripps Clinic & Res. Found. v. Genentech, Inc., 18 USPQ2d 101 (Fed. Cir. 1991).

As amended, the claims are directed, *inter alia*, to a system for use in combination with an extracorporeal blood flow circuit, the system comprising: a) one or more automated sensor modules adapted to monitor, directly or indirectly, the presence of one or more blood analytes, and b) one or more regulating modules adapted to affect the presence, concentration and/or activity of one or more blood analytes, wherein the sensor module is adapted to incorporate flow injection analysis ("FIA") techniques, and comprises: i) a blood withdrawal component with in-line access, ii) an analytical component, and iii) a readout component.

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Arp discloses a blood pump and oxygenator monitor-controller and display device (abstract). However, there is nothing in Arp that discloses a sensor module adapted to incorporate flow injection analysis ("FIA") techniques, comprising: i) a blood withdrawal component with in-line access, ii) an analytical component, and iii) a readout component. Thus, Arp does not anticipate the presently pending claims.

Withdrawal of the 35 U.S.C. §102(b) rejection of the claims as being anticipated by Arp is therefore respectfully requested.

*The 35 U.S.C. § 103(a) Rejection*

The Examiner rejected claims 8, 15 and 18-19 under 35 U.S.C. §103(a) as being unpatentable over Arp in view of Grandics *et al.* (International publication No. WO 96/35954). The cancellation of claim 15 renders this rejection to claim 15 moot. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves, or in the knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed invention. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. M.P.E.P. § 2143. The teaching or suggestion to arrive at the claimed invention and the reasonable expectation of success must be found in the prior art, not in Applicant's disclosure. M.P.E.P. § 2143 citing with favor *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

There is no disclosure or suggestion in Arp of a sensor module adapted to incorporate flow injection analysis ("FIA") techniques, comprising: i) a blood withdrawal component with in-line access, ii) an analytical component, and iii) a readout component. Therefore, Arp does not render the pending claims obvious.

Grandics *et al.* do not remedy the deficiencies of Arp. Grandics *et al.* disclose a method and device for removal of heparin from whole blood during extracorporeal therapy (abstract).

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However, there is nothing in *Grandics et al.* that discloses or suggests the invention as presently claimed. Hence, the pending claims are not obvious in view of *Grandics et al.*

Withdrawal of the 35 U.S.C. §103(a) rejection of the claims as being unpatentable over *Arp* in view of *Grandics et al.* is therefore respectfully requested.

*Double Patenting Rejection*

The Examiner rejected claims 1-20 under the judicially created doctrine of obviousness-type double patenting over claims 1-8, 10-11 and 30-39 of U.S. Patent No. 6,733,471. The cancellation of claims 3-6 and 13-16 renders this rejection of claims 3-6 and 13-16 moot. While not conceding to the obviousness of the presently pending claims over claims 1-8, 10-11 and 30-39 of U.S. Patent No. 6,733,471, a terminal disclaimer is filed herewith. Withdrawal of the obviousness-type double patenting rejections is respectfully requested.

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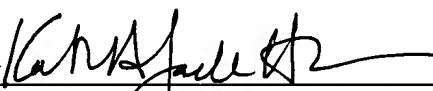
**CONCLUSION**

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is invited to contact the undersigned attorney at 763-391-9634.

Please charge any additional required fees or credit any overpayment to Deposit Account No. 13-2546.

Respectfully submitted,

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